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SIPDIS

DEPT FOR AF/S; AF/EPS; AF/EPS/SDRIANO  
DEPT FOR S/OFFICE OF GLOBAL AIDS COORDINATOR  
STATE PLEASE PASS TO USAID FOR GLOBAL BUREAU APETERSON  
DEPT FOR USAID GH/OHA/CCARRINO AND RROGERS, AFR/SD/DOTT  
ALSO FOR AA/EGAT SIMMONS, AA/DCHA WINTER  
HHS FOR THE OFFICE OF THE SECRETARY, WSTEIGER AND NIH, HFRANCIS  
CDC FOR SBLOUNT AND EMCCRAY

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SUBJECT: SOUTH AFRICA PUBLIC HEALTH JANUARY 28 ISSUE

#### Summary

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1. Summary. Every two weeks, USEmbassy Pretoria publishes a public health newsletter highlighting South African health issues based on press reports and studies of South African researchers. Comments and analysis do not necessarily reflect the opinion of the U.S. Government. Topics of this week's newsletter cover: Rationing ARV Treatment; Industry Anti-retroviral Treatment Low; Two African Herbal Medicines Inhibit Metabolism of Anti-HIV Drugs; Improving the Quality of Primary Health Care: Public and Private Provision; Release of Mortality Report Delayed; Draft Legislation Regulating Alternative Medicines Likely to be Changed; and Aspen Approved by U.S. FDA. End Summary.

#### Rationing ARV Treatment

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2. Researchers from the Center for International Health and Development and the Clinical HIV Research Unit at the University of the Witwatersrand recently published an article describing how rationing of antiretroviral therapy (ART) will be necessary as long as demand exceeds supply. In Zambia, the first-year target for treatment is 10,000 patients; while 100,000 Zambians have already reached the clinical threshold of less than 200 CD4 cells. The most recent numbers of South Africans receiving ART is 19,500 by October 2004, out of an estimated 300,000 to 700,000 needing ART treatment (South African government estimates). Kenya's target is 50 percent coverage, as is the global target of WHO's 3X5 initiative. Rationing is any policy that restricts consumption and can be either a market-based (relying on prices) or non-market system. As long as treatment targets represent less than total HIV/AIDS patients, the rationing of treatment is inevitable.

3. The article discusses rationing options and evaluation of rationing systems and recommends that governments should make deliberate choices about rationing ART and then explain and defend the choices to their constituencies. The most accepted criterion for rationing ART is disease progression. WHO guidelines call for ART when a patient has a CD4 cell count of less than 200; although a recent study highlighted how changing this criteria would impact demand in South Africa. If ART treatment guidelines were changed to a CD4 count of 350 (the guidelines used by the U.S. Department of Health and Human Services), the proportion of HIV-positive people eligible for therapy would increase from 9.5 percent to 56.3 percent.

4. The authors describe four types of rationing systems: two explicit and two implicit. Explicit rationing systems use specific socioeconomic criteria to define populations that receive treatment. An example is the mother to child transmission program that makes ART preferentially available to HIV-positive mothers and their children. Other explicit systems of rationing include either co-payment requirement or geographic location, where clinics are concentrated in high HIV-infected regions. Other systems ration ART implicitly, with either a lack of medical facilities or drugs effectively serving as rationing in particular areas. A system requiring queues will be implicit rationing. The authors provide seven criteria for assessing rationing systems that could help governments decide on their effectiveness. The criteria outlined include: (1) Does the rationing system produce a high rate of successfully treated patients; (2) Is the cost per patient relatively low; (3) Are the human and infrastructural resources needed for program implementation available; (4) To what extent does the system of distributing treatment reduce the long-term effects of HIV/AIDS on economic development; (5) Do all medically eligible patients have equal access to treatment; (6) Can the system be sustained; and (7) Does the treatment reduce the rate of HIV infection. The authors recommend that governments make clear that the treatment program chosen be clear in its explicit and implicit means of rationing so people can debate the policy choices. Source: Health-link Bulletin, January 14; [www.thelancet.com](http://www.thelancet.com).

15. A study, "Treatment of HIV/AIDS at SA's Largest Employers: Myth or Reality" done by the Center for International Health and Development, shows that 4 percent of employees in South Africa's largest companies are on HIV/AIDS disease management programs and 0.6 percent receive antiretroviral treatment despite an HIV prevalence rate of 14.3 percent. Only 25 of South Africa's 64 largest firms know how many employees are enrolled in their HIV/AIDS disease management programs or are receiving ARV treatment. Table 1 highlights treatment results from the study by industrial sector. Only a few companies make up the most of the 3,908 workers receiving ARV treatment. For example, Anglo American has more than 1,000 of its South African employees on treatment. Study authors attribute low treatment numbers to stigma, and to new workplace programs. In addition, companies have waited to see how the government program prioritizes its treatment program, seeing if the government's program would reach their employees. The mining and financial services sectors lead in providing HIV/AIDS services. All financial services and 75 percent of mining firms surveyed offer ARV treatment to employees. Only 31 percent of retail firms and no construction companies offer ARV treatment. Companies with in-house HIV/AIDS management programs get more people into treatment than those companies relying on medical insurance programs. Source: FM Focus, January 14.

Table 1. Industrial Employees on ARV Treatment by Industry

Sector	Number of Employees	Employees on ARV Treatment
Mining	275,300	2,954
Financial	172,000	300
Transport, Construction and Communication	119,000	6
Retail	44,900	52
Manufacturing	36,700	518
Agriculture	8,475	48
Total	656,375	3,908

Two African Herbal Medicines Inhibit Metabolism of Anti-HIV Drugs

16. Two herbs widely used to treat individuals with HIV in Africa have a significant interaction with anti-HIV medication, potentially leading to poor metabolism of anti-retrovirals, according to a study published in the January 3rd edition of AIDS. Extreme caution should be taken if using herbal medicines in the treatment of HIV, stress the investigators, who also state that their study shows the importance of undertaking pharmacokinetic studies to show the potential interactions between herbal medication and antiretrovirals.

17. The South African government has accredited 27 facilities to provide nutritional and micronutrients supplements and complementary and traditional medicines to HIV-positive patients so that the progression of HIV disease slows. Many anti-HIV drugs, including protease inhibitors and non-nucleoside reverse transcriptase inhibitors (NNRTIs) are metabolized using the CYP3A4 pathway. Herbal medicines have been shown to affect levels of anti-HIV because of their impact on CYP3A4 and, in the case of protease inhibitors, P-glycoprotein as well. Some herbal medications are also known to interact with nuclear receptors such as the pregnane X receptor (PXR), which modulates expression of CYP3A and P-glycoprotein. In a laboratory study investigators examined the effects of Hypoxis hemerocallidea (African potato) and Sutherlandia, two herbs widely used against HIV in Africa, on the metabolism of antiretroviral drugs. Capsules, tablets and teas of both herbs were extracted and tested for their ability to inhibit CYP3A4. The affect of the herbs on PXR and P-glycoprotein were also assessed. African potato showed a significant inhibition of CYP3A4 activity. Sutherlandia also inhibited CYP3A4. In addition, African potato and Sutherlandia resulted in significant activation of PXR. The investigators suggest that using these herbal drugs with antiretroviral agents may result in the early inhibition of drug metabolism and transport followed by the induction of decreased drug exposure with more prolonged therapy. The authors underscore the need for appropriately designed pharmacokinetic studies to discover the interaction potential of herbal drugs with antiretroviral drugs. Failure to undertake such studies could result in drug interactions, treatment failure, resistant HIV, and drug toxicities. Source: Healthnet.org, Mills E et al. Impact of African herbal medicines on antiretroviral metabolism, AIDS 2005, January 14. Improving the Quality of Primary Health Care: Public and Private Provision

18. Research from the London School of Hygiene and Tropical

Medicine, the University of Witwatersrand and the University of Cape Town examines the performance of various types of public health care (PHC) provision in South Africa. It attempts to determine the strengths and weaknesses of private and public provision of primary care and the potential for increased arrangements between the public and private sectors. It assesses whether private providers give good quality service at a cost that is comparable to that of the public sector. The different models considered were individual General Practitioner (GP) contracts, commercial companies running PHC clinics on contracts, physicians in independent or group practices, commercial companies running clinic chains, and the public integrated model of clinics. Performance was measured by looking at the cost and quality of providers in terms of their infrastructure, treatment given and acceptability to patients.

9. The main findings of the report were the following: (1) care delivered by two of the private provider models, contracted GPs and the clinic chain, was comparable to public sector care in terms of cost per patient; (2) there were no private care provider models that consistently showed a better overall technical quality of care than public clinics. Care by GPs lacked standardization and the clinic chain failed to deliver standardized chronic care; (3) users perceived the quality of service of private providers, except for contracted GPs, to be far superior to that of others; (4) the performance of both models involving contracts was negatively impacted by weak contract design and implementation.

10. The quality of PHC delivered to people in developing countries is often poor and coverage is not yet universal. This is despite a focus on the public delivery of comprehensive PHC over the past 20 years. People frequently consult private providers including qualified medical professionals and unqualified health practitioners. A better use of private care providers, therefore, might be a potential solution, including contracting them to provide services on behalf of the public sector. Performance was strongly influenced by the context of each type of service provision and thus simply comparing public with private providers was not helpful. Source: Healthnet.org, January 14, "The performance of different models of primary care provision in Southern Africa", Social Science & Medicine, Vol. 59.

#### Release of Mortality Report Delayed

11. The release of a mortality report by Statistics SA (Stats SA) has been delayed to ensure it is "a good and useful product", a senior agency official said yesterday, but would not specify when it would be made public. The report, detailing causes of deaths between 1997 and 2003, was due for release on January 12, but was postponed at the last minute without explanation, fuelling speculation of political interference. The report will include AIDS deaths figures, which has sparked controversy in the past between government, Stats SA and the Medical Research Council. Stats SA had said the report was based on all death notification forms received from home affairs from 1997 to 2003. Stats SA's last report in 2001 was based on a 12 percent sample of forms from 1997 to 2001. It said "basic information" on causes of deaths would be presented for 1997 to 2003, and a more detailed analysis for 1997, 1999 and 2001. In 2001, Stats SA released a report showing a sharp increase in deaths among sexually active youths over the previous 15 years, saying this was largely due to AIDS, which, it said, was responsible for the deaths of an estimated 40 percent of people aged 15 to 49. At that time, the report was widely criticized by the Health Department and the Presidency saying that no proof that AIDS was responsible for the rise in deaths. Stricter coding procedures and more efficient methods were used for the upcoming study to determine underlying causes of death, ranked according to frequency, and 10 leading causes presented for various populations and sub-populations. Source: Business Day, January 20.

#### Draft Legislation Regulating Alternative Medicines Likely to be Changed

12. Current draft regulations state that alternative medicines should be regulated in the same way as patented conventional drugs. Health Minister Manto Tshabalala-Msimang recently suggested that this draft legislation is likely to be changed, meaning that African traditional medicines, homoeopathic remedies, Chinese and Ayurvedic medicines and others would not have to go through the rigorous testing as pharmaceutical drugs. If this draft were passed into law, alternative medicines would have to undergo trials designed for Western medicines and a pharmacist would have had to oversee their manufacture. Experts say complementary medicine cannot afford expensive, large-scale trials because alternative medicines are not patented. At least 80 percent of South Africans used African, Chinese, Ayurvedic or South American traditional medicines, she said. The proportion would be greater if homoeopathic and other complementary medicines were included.

South Africans spent R3-billion a year on complementary medicines. Tshabalala-Msimang said the study of indigenous knowledge was "an opportunity to reclaim Africa's scientific and socio-cultural heritage, which was stigmatized and discredited as primitive rituals and witchcraft by colonialism and apartheid". The Health Department has spent R6 million (\$1 million, using 6 rands per dollar) into the testing of the safety, efficacy and quality of traditional medicines that are used as immune boosters by people with HIV and Aids. The first phase of testing the safety of one of these medicines was completed late in 2004 and the research had shown promising results, the health minister said. The government also funds research at universities and science councils into the efficacy of traditional medicines used to treat tuberculosis, malaria, asthma, cancer, diabetes, anxiety, stress and musculoskeletal disorders. (The Mercury, January 17)

Aspen Approved by U.S. FDA

13. Aspen Pharmacare had won U.S. Federal Drug Administration (FDA) regulatory approval for its AIDS drugs to be included in the U.S.'s \$15 billion AIDS program. "The approval is for the co-packed and most widely used triple cocktail combination of Lamivudine/Zidovudine and Nevirapine tablets in conventional adult dosages and Aspen stated that the drugs would be priced at affordable levels. Aspen is the first accredited generic supplier to the U.S. AIDS program. Production would soon begin at factory in Port Elizabeth, approved by the FDA in December. The triple combination drug would not be immediately available in South Africa, as it was still awaiting approval from the Medicines Control Council, which was expected soon. While the result of the South African Health Department's first anti-retroviral bid has not been released, Aspen officials believe that the company is well positioned to win the bid. About 25.4 million people live with HIV in Africa - where just three percent of those infected had access to life-prolonging ARV drugs. At least 2.3 million people died from the disease in sub-Saharan Africa in 2004. Aspen's pioneering of ARVs on the African continent and its world first generic ARV recognition by the FDA was achieved after getting voluntary licenses from the original drug manufacturers. These include GlaxoSmithKline, the world's leading supplier of HIV and AIDS drugs, German drug maker Boehringer Ingelheim and Bristol-Myers Squibb. By close of business on January 25, shares in Aspen increased 4.4 percent to R19.84 per share. Source: Business Day; Business Report; The Star; allAfrica.com; January 26.

AIDS Treatment Numbers Released

14. As of September 2004, 155,000 people received anti-retroviral treatment under the Presidential Emergency Plan for AIDS Relief, a program begun in 2003. South Africa is one of 15 focus nations, with over 12,000 receiving anti-retroviral treatment. World Health Organization released estimates of people receiving anti-retroviral treatment and those aged 15-49 needing treatment. In Sub-Saharan Africa there were 310,000 receiving therapy while 4 million need it. According to WHO, 700,000 receive therapy globally while 5.8 million need it. Source: The Citizen, January 27; U.S. Embassy Pretoria PAS Press Release, January 26.

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